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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,707	01/19/2001	Margaret E. Moon	576.02-US	7215

7590

02/25/2003

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,707

Applicant(s)

MOON ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 January 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 7 of claim 1, the phrase "the sample receiving portion" lacks antecedent basis since earlier in the claim, a sample receiving surface is positively recited. Claim 1 is incomplete since the last step of the method (i.e. correlating the appearance of the dried sample with a reference) does not refer back to the determination of a woman's fertility status as recited in the preamble of claim 1.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-2 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Orell-Porrazzo et al (WO 97/23798, submitted in the Information Disclosure Statement dated February 2, 2001).

Orell-Porrazzo et al teach of a method for determining a woman's fertility status which comprises the steps of providing an optical system having a sample receiving surface and an eyepiece, collecting a sample of bodily fluid from a woman, depositing the sample on the sample receiving surface, drying the sample, inspecting the sample using the optical system and correlating the appearance of the dried sample with a reference. The dried sample is inspected for a tell-tale, visual reference pattern of key, universal fertility carriers. A female secretion such as saliva is collected on a test area section 30 of the optical system. This test area section 30 serves as an integrated microscope stage. The saliva sample is allowed to dry completely. A viewing section 10 of the device is then rotated over the test area section 30 so that a user may visualize the pattern of fertility carriers in the sample of saliva. A central connecting joint 25 is located between the test area section 30 and the viewing section 10. This connecting joint 25 forms a rotating joint of determined fixed distance between the viewing section 10 and the testing area section 30. This fixed distance 80 is selected to form an optimal viewing focal length between the microscope bead lens 15 and testing area section 30 of focal length 75. In the manufacturing process, the length of central connecting joint 25 and of its central connecting post 65 are made to the specification of distance 80 to accommodate focal length 75. In this way, the saliva sample is consistently viewed in focus through the optical system without having to alter the distance between the viewing section 10 and the test area section 30. The optical

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system may comprise a multi-lens system since multiple microscope bead lens 15 could be included consisting of different diameters creating different magnifying powers. In addition, an objective lens 23 and focusing lens 21 could be substituted for microscope bead lens 15, which are fashioned with a suitable focal length to provide a fixed focus to the test area section 30 and affording a magnifying power suitable to observe universal fertility carrier patterns.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 3-11 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orell-Porrazzo et al (WO 97/23798) in view of Cho (US Patent no. 5,572,370, submitted in the Information Disclosure Statement filed on February 2, 2001). For a teaching of Orell-Porrazzo et al, see previous paragraphs in this Office action. Orell-Porrazzo et al fail to teach of a protective cover over the optical system, different geometrical arrangements for the optical system, and comparing the image of the dried saliva sample to a reference chart comprising a reference image from a fertile period, from a transition period and from an infertile period.

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Cho teaches of a method and apparatus for determining a woman's fertile periods, which comprises a hollow housing that sealably contains an optical system and a saliva specimen slide. The optical system is used to closely view patterns formed on the specimen slide by the saliva after it has dried and crystallized on the slide. The patterns are then compared with standard comparison patterns to determine the woman's present fertility status. The standard comparison patterns include patterns from an infertile period, a fertile period and a transition period. See lines 12-25 in column 5 of Cho. The device taught by Cho also has a cap member 60 that can be placed over the body portion 22a when the device is not in operation. The optical system has a lens assembly comprising a ring-shaped member 35 within which a pair of convex lens 36a and 36b are mounted. Cho teaches that various different known types of lenses in various configurations may be used in the device and method.

Based upon a combination of Orell-Porrazzo et al and Cho, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to compare the pattern from the dried saliva sample taught by Orell-Porrazzo et al with standard patterns representing a fertile state, an infertile state and a transition state, as taught by Cho, so as to accurately assess the fertility status of the woman tested and determine what fertility state she is currently in. It also would have been obvious to one of ordinary skill in the art to provide the optical system taught by Orell-Porrazzo et al with a protective cover such as the cap 60 disclosed in the device of Cho, so as to keep the optical system clean and protect the optical system from damage. It also would have been obvious to one of ordinary skill in the art to provide the optical system taught by Orell-Porrazzo et al with different geometrical arrangements and with different known components such as a condenser or filter since Cho discloses that different known types of lenses

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in various configurations may be utilized in an optical system used to assess the fertility status of a woman.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Canter et al, Soldini (WO 95/28130) and Deljanin (WO 98/19197) who teach of different methods and devices to determine a woman's fertility.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 703-308-3912. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

February 20, 2003

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP 1700